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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,884	01/24/2002	Han Chang	D0076 NP	3042

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EXAMINER
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ART UNIT	PAPER NUMBER
1647	6

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/056,884	CHANG ET AL.	
	Examiner	Art Unit	
	Christopher Nichols, Ph.D.	1647	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-25* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 (in part), 2-4, 8, 9, 16 (in part), 17, 18, and 19 drawn to a method of making a polypeptide, including an **isolated nucleic acid molecule** comprising SEQ ID NO: 1, fragments, variants, vectors, and host cells comprising same classified in class 536, subclass 325, for example.

II. Claims 1 and 16 (in part), drawn to a complementary sequence of the isolated nucleic acid molecule comprising SEQ ID NO: 1 (**antisense**), classified in class 536, subclass 24.5, for example.

III. Claims 5-6, 10, and 20 drawn to an isolated **polypeptide** comprising SEQ ID NO: 2, fragments, variants, homologues, muteins comprising same, classified in class 530, subclass 350, for example.

IV. Claim 7, drawn to an **antibody**, classified in class 530, subclass 387.1 for example.

V. Claim 11 and 21 (each in part), drawn to a method for preventing, treating, or ameliorating a medical condition, comprising the step of administering to a mammalian subject a therapeutically effective amount of a *polypeptide*, wherein the medical condition is a neural disorder related to **memory deficiency**, classified in class 514, subclass 2, for example.

VI. Claim 11 and 21 (each in part), drawn to a method for preventing, treating, or ameliorating a medical condition, comprising the step of administering to a

mammalian subject a therapeutically effective amount of a *polynucleotide*, wherein the medical condition is a neural disorder related to **memory deficiency**, classified in class 514, subclass 44, for example.

VII. Claim 11 and 22 (each in part), drawn to a method for preventing, treating, or ameliorating a medical condition, comprising the step of administering to a mammalian subject a therapeutically effective amount of a *polypeptide*, wherein the medical condition is a neuroendocrine condition related to **aberrant thyroid hormone release**, classified in class 514, subclass 2, for example.

VIII. Claim 11 and 22 (each in part), drawn to a method for preventing, treating, or ameliorating a medical condition, comprising the step of administering to a mammalian subject a therapeutically effective amount of a *polynucleotide*, wherein the medical condition is a neuroendocrine condition related to **aberrant thyroid hormone release**, classified in class 514, subclass 44, for example.

IX. Claim 11 and 23 (each in part), drawn to a method for preventing, treating, or ameliorating a medical condition, comprising the step of administering to a mammalian subject a therapeutically effective amount of a *polypeptide*, wherein the medical condition is a disorder related to **hyper potassium channel activity**, classified in class 514, subclass 2, for example.

X. Claim 11 and 23 (each in part), drawn to a method for preventing, treating, or ameliorating a medical condition, comprising the step of administering to a mammalian subject a therapeutically effective amount of a *polynucleotide*,

wherein the medical condition is a disorder related to **hyper potassium channel activity**, classified in class 514, subclass 44, for example.

XI. Claim 11 and 24 (each in part), drawn to a method for preventing, treating, or ameliorating a medical condition, comprising the step of administering to a mammalian subject a therapeutically effective amount of a *polypeptide*, wherein the medical condition is an **immune disorder**, classified in class 514, subclass 2, for example.

XII. Claim 11 and 24 (each in part), drawn to a method for preventing, treating, or ameliorating a medical condition, comprising the step of administering to a mammalian subject a therapeutically effective amount of a *polynucleotide*, wherein the medical condition is an **immune disorder**, classified in class 514, subclass 44, for example.

XIII. Claim 11 and 25 (each in part), drawn to a method for preventing, treating, or ameliorating a medical condition, comprising the step of administering to a mammalian subject a therapeutically effective amount of a *polypeptide*, wherein the medical condition is an immune disorder related to **aberrant NF-κB activity**, classified in class 514, subclass 2, for example.

XIV. Claim 11 and 25 (each in part), drawn to a method for preventing, treating, or ameliorating a medical condition, comprising the step of administering to a mammalian subject a therapeutically effective amount of a *polynucleotide*, wherein the medical condition is an immune disorder related to **aberrant NF-κB activity**, classified in class 514, subclass 44, for example.

XV. Claim 12, drawn to a method of diagnosing a pathological condition or a susceptibility to a pathological condition in a subject comprising determining the presence or absence of a mutation in a **polynucleotide**, classified in class 435, subclass 6, for example.

XVI. Claim 13, drawn to method of diagnosing a pathological condition or a susceptibility to a pathological condition in a subject comprising determining the presence or absence of a mutation in a **polypeptide**, classified in class 435, subclass 7.1, for example.

XVII. Claim 14, drawn to a **process for making polynucleotide sequences** encoding a gene product having altered potassium channel beta subunit activity, classified in class 435, subclass 455, for example.

XVIII. Claim 15, drawn to a **shuffled polynucleotide**, classified in class 536, subclass 23.1, for example.

2. The inventions are distinct, each from the other because of the following reasons:

3. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions I, V, VI, VII, VIII, IX, X, XI, XII, XIII, XIV, XV, XVI, XVII, and XVIII are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires search and consideration of determining **recombinant synthesis of a polypeptide**, which is not required by any of the other Inventions.

Invention V requires search and consideration of determining using a *polypeptide* to treat a **memory deficiency**, which is not required by any of the other Inventions. Invention VI requires search and consideration of determining using a *polynucleotide* to treat a **memory deficiency**, which is not required by any of the other Inventions. Invention VII requires search and consideration of determining using a *polypeptide* to treat **aberrant thyroid hormone release**, which is not required by any of the other Inventions. Invention VIII requires search and consideration of determining using a *polynucleotide* to treat **aberrant thyroid hormone release**, which is not required by any of the other Inventions. Invention IX requires search and consideration of determining using a *polypeptide* to treat **hyper potassium channel activity**, which is not required by any of the other Inventions. Invention X requires search and consideration of determining using a *polynucleotide* to treat **hyper potassium channel activity**, which is not required by any of the other Inventions. Invention XI requires search and consideration of determining using a *polypeptide* to treat an **immune disorder**, which is not required by any of the other Inventions. Invention XII requires search and consideration of determining using a *polynucleotide* to treat an **immune disorder**, which is not required by any of the other Inventions. Invention XIII requires search and consideration of determining using a *polypeptide* to treat **aberrant NF-κB activity**, which is not required by any of the other Inventions. Invention XIV requires search and consideration of determining using a *polynucleotide* to treat **aberrant NF-κB activity**, which is not required by any of the other Inventions. Invention XV requires search and consideration of determining the presence or absence of a mutation in a **polynucleotide**, which is not required by any of the other Inventions. Invention XVI requires search and consideration of determining the presence or absence of a

mutation in a **polypeptide**, which is not required by any of the other Inventions. Invention XVII requires search and consideration of **gene shuffling**, which is not required by any of the other Inventions.

4. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Inventions II, III, IV, and XVIII are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. The **antisense molecule of Invention II** is independent and distinct from the products of Inventions III, IV, and XVIII because none are required to make or use the antisense molecule of Invention II. The **polypeptide of Invention III** is independent and distinct from the products of Inventions II and XVIII because neither is required to make or use the polypeptide of Invention III. Further, the polypeptide of Invention III can be prepared by processes which are materially different from antibody of Invention IV, such as by chemical synthesis, or by isolation and purification from natural sources. The **antibody of Invention IV** is independent and distinct from the products of Inventions II and XVIII because neither is required to make or use the antibody of Invention II. Although the antibody of Invention IV can be used to obtain the polypeptide of Invention III, it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. The **gene-shuffling product of Invention XVIII** is independent and distinct from the products of Inventions II, III, and IV because none are required to make or use the gene-shuffling product of Invention XVIII.

5. Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the **polypeptide** of Invention III can be made through materially different methods such as chemical synthesis or isolation from natural sources.

6. Inventions XVII and XVIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the **shuffled gene product** of Invention XVIII can be made through materially different methods such as chemical synthesis or isolation from natural sources.

7. Inventions III and V, VII, IX, XI, XIII, and XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the **polypeptide** of Invention III can be used in materially different processes such as biochemical assays or to isolate receptor or binding partners (yeast-two hybrid system).

8. Inventions II and each of I, V, VI, VII, VIII, IX, X, XI, XII, XIII, XIV, XV, XVI, and XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or

different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions II and each of I, V, VI, VII, VIII, IX, X, XI, XII, XIII, XIV, XV, XVI, and XVII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, V, VI, VII, VIII, IX, X, XI, XII, XIII, XIV, XV, XVI, and XVII do not recite the use or production of the **antisense molecule** of Invention II.

9. Inventions III and each of VI, VIII, X, XII, XIV, XV, and XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions III and each of VI, VIII, X, XII, XIV, XV, and XVII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions VI, VIII, X, XII, XIV, XV, and XVII do not recite the use or production of the **polypeptide** of Invention III.

10. Inventions IV and each of I, V, VI, VII, VIII, IX, X, XI, XII, XIII, XIV, XV, XVI, and XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions IV and each of I, V, VI, VII, VIII, IX, X, XI, XII, XIII, XIV, XV, XVI, and XVII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, V, VI, VII, VIII, IX, X, XI, XII, XIII, XIV, XV, XVI, and XVII do not recite the use or production of the **antibody** of Invention IV.

11. Inventions XVIII and each of I, V, VI, VII, VIII, IX, X, XI, XII, XIII, XIV, XV, and XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable

of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions XVIII and each of I, V, VI, VII, VIII, IX, X, XI, XII, XIII, XIV, XV, and XVI are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, V, VI, VII, VIII, IX, X, XI, XII, XIII, XIV, XV, and XVI do not recite the use or production of the **shuffled gene product** of Invention XVIII.

12. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Elyabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

CJN
April 18, 2003